

**Best Practices in Regulatory Development**  
A Conference for Federal Regulatory Professionals

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**Conference Proceedings**

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## Acronyms

DOC	Department of Commerce
DOT	Department of Transportation
ELVS	End of Life Vehicle Solutions Corporation
EPA	U.S. Environmental Protection Agency
FACA	Federal Advisory Committee Act
FDMS	Federal Docket Management System
FOIA	Freedom of Information Act
FR	<i>Federal Register</i>
IT	Information technology
MOU	Memorandum of Understanding
NOAA	National Oceanic and Atmospheric Administration
NPRM	Notice of proposed rulemaking
OFR	Office of the Federal Register
OGC	Office of General Counsel
OMB	Office of Management and Budget
ORD	Office of Research and Development
OSHA	Occupational Safety and Health Administration
PRIME	Paperwork and Regulation Information Management Environment
RFA	Regulatory Flexibility Act
RPR	Rulemaking Project Record
SBA	U.S. Small Business Administration
SBREFA	Small Business Regulatory Enforcement Fairness Act of 1996
VSO	Veterans Service Organization

## Introduction

"Best Practices in Regulatory Development: A Conference for Federal Regulatory Professionals" was held in Washington, DC, in August 2007. The U.S. Environmental Protection Agency (EPA) sponsored the conference, and more than 130 federal regulatory professionals attended representing 20 federal agencies. The event was designed to provide a forum for various federal agencies to share best practices that can improve the future of regulatory development. Throughout the two-day event, participants were encouraged to exchange information, identify needs and issues, and think creatively.

Following opening remarks, the conference started with a "town hall" discussion with three leading experts in regulatory development. The agenda continued with sessions on agency processes, stakeholder involvement, negotiated rulemaking, technology for addressing public comments, collaborative programs, and efficiency in regulatory development. After each session, roundtable discussions provided the opportunity for participants to engage in an in-depth question/answer period with each presenter. The conference closed with an informal session at which the EPA Deputy Associate Administrator for Policy, Economics, and Innovation shared parting thoughts on a path forward, and participants voted on key themes and action items identified during the conference.

This document provides a brief summary of the conference sessions, with particular emphasis on the points of discussion, suggested action items, and other needs identified. The views and opinions expressed in this document are those of the presenters and participants and are not necessarily the views of EPA. For more information on the conference, including PowerPoint presentations from many of the presenters discussed here, please refer to the conference agenda and presentations, which are available on the EPA Office of Policy, Economics, and Innovation Web site at [www.epa.gov/opei/regconf/index.html](http://www.epa.gov/opei/regconf/index.html).

## Setting the Stage

*John Morrall, Office of Management and Budget*

John Morrall opened the conference by presenting the [Office of Management and Budget \(OMB\)](#) perspective on best practices in regulatory development. He began by stating that OMB's goal is to help the public and improve the outcomes of regulations. Although OMB does not directly seek to help agencies improve their regulatory development processes, OMB supports such efforts because a better process is likely to lead to better regulatory outcomes.

Under [Executive Order 12866](#), as amended, agencies must choose the regulatory alternative that maximizes net benefits. Agencies must quantify the costs and benefits of a regulation, and benefits must justify the costs. [OMB Circular A-4](#) assists agencies by defining good regulatory analysis and standardizing the way benefits and costs of federal regulatory actions are measured and reported. OMB believes it is critical to accurately know the cost of regulatory actions in order to fairly inform the public and Congress.

Morrall predicts that supporting analyses for regulatory actions will improve over the coming years. Using the past to predict the future, analyses have become much more sophisticated since the use of inflation impact statements in the 1970s, more recent cost-benefit analyses, and a current trend toward cost-effectiveness analyses. Current analyses are consistent with modern economic thought, and analyses today are more thorough and consider more factors of the regulation.

Economic analyses of regulations are performed worldwide, and U.S. practices serve as a model for many countries. Morrall expects international applications of economic analyses will continue. He also expects that in the future, agencies will use less pure cost-benefit analysis, moving instead to cost-effectiveness analysis. Finally, agencies should expect that the emphasis on transparency in government will continue.

## The Challenge: What Will the Regulatory Development Process Look Like in 25 Years?

Three leading experts in the regulatory development field answered the question: What will the regulatory development process look like in 25 years? Each panelist provided brief remarks (summarized below) on the future of the process and likely innovations in both regulatory development and public engagement. Afterwards, conference participants asked questions, challenged remarks, and established a dialogue that set the stage for the conference.

*Cynthia Farina, Cornell University*

Predicting what the regulatory development process will look like in 25 years presents us with a unique challenge. In truth, it is difficult to anticipate how the process might change in even the next 5, 10, or 15 years. Farina noted that the process of rulemaking is largely experimental, and rule writers – both future and current – need to be open-minded, creative, flexible, and resourceful. Future rulemaking processes should focus on collaboration and communication between non-governmental organizations, all levels of government (local, state, and federal), and the general public. Current government requirements make this kind of communication and experimentation difficult.

Farina recommended that [E-Rulemaking](#) offers one example of a new and innovative approach that emphasizes cross-collaboration between various governmental and non-governmental entities, and also takes advantage of current technological developments by encouraging communication between information technology (IT) staff and regulators. According to Farina, such efforts are the building blocks with which an improved regulatory development process can be built.

*Neil Kerwin, American University*

Regulatory development is not currently recognized as a profession, and it is often considered as a secondary job function. Further, there is no professional association for rule writers, which could provide support, training, and structure similar to that available to other professions, such as economics or law. Kerwin argued that the regulatory development process is not likely to improve until the profession is formally recognized, and leaders, lawmakers, and the public value the process. When both the process and outcomes are valued, there will be sufficient organization and support for professional rule writers to actively improve the process.

Currently, the public does not recognize that most standards come from regulations promulgated by administrative agencies rather than laws passed by Congress. Regulatory development consists of three fundamental dimensions: information, participation, and accountability. In the future, rule writers should emphasize and strengthen these dimensions while developing regulations.

*Rick Otis, Environmental Protection Agency*

Understanding the regulatory process requires that we understand where the process has been, where it is currently, and where it is headed. The government workforce is currently in a state of transition where many veteran employees are nearing retirement. As a result, years of valuable experience and understanding of the regulatory process will be lost. Although a younger workforce offers the ability to apply new and innovative reasoning to the perennial problem of developing effective regulations, Otis emphasized that there is a great need for improved training in the development process for new government employees.

Aside from retirement, agencies are also faced with legislative authorities that were written decades ago, when the world's problems looked very different than they do today. For example, EPA has produced a large volume of regulations, and Otis predicted that EPA's future work will often involve re-evaluating outdated regulations.

## Summary of Town Hall Discussion

Issues concerning how to identify, engage, and educate targeted audiences were the main focus of the question and answer period. Panelists acknowledged that the Internet offers a great communication tool, but noted that tools such as eRulemaking hold mostly undeveloped potential because Congress and the public do not often recognize the importance of accurately and efficiently managing the regulatory development process. As a result, there is a lack of funding and other support needed for the development of such tools.

Participants also emphasized the need for non-Web-based tools, such as guides and educational training programs. However, panelists agreed that communication, Web-based or otherwise, works best if the proper targeted audience is identified and encouraged to participate early in the developmental process. Early public engagement will translate to a greater number of sensitive issues being addressed early on, avoiding time and controversy later in the process.

Panelists further commented that agencies today are doing a great job with the resources they currently have. However, recognizing the points brought up during today's discussion, the aim of this conference should be to help ignite creativity and improve upon the regulatory process over the next 25 years.

## Engaging the Public in Rulemaking

This session featured three presentations and focused on the roles for small businesses, local governments, and non-governmental organizations in the rulemaking process. Short summaries for each presentation are provided, along with a summary of the roundtable discussion that followed.

### Engaging Small Businesses

*Tom Sullivan, U.S. Small Business Administration*

Tom Sullivan is Chief Counsel in the [Small Business Administration \(SBA\) Office of Advocacy](#). He described the Office of Advocacy's role in supporting the interests of small businesses during the rulemaking process. SBA does not develop any rules itself. The Office of Advocacy is an independent office consisting of a small group of researchers and regulatory economists who document the benefits of small businesses to the world community by gathering data and producing numerous reports. Their work is often used specifically in implementing the [Regulatory Flexibility Act \(RFA\)](#) (5 U.S.C. 601 *et seq*).

The RFA exists because of the disproportionate economic effects that regulations often have on small businesses – small businesses tend to have fewer legal/policy staff, so it may take business owners more time to understand and comply with regulations than it would for a larger business. The RFA requires an agency promulgating a rule to analyze and consider the impact of the rule on small entities, and to consider alternatives to the proposed rule that would minimize any significant impact.

The [Small Business Regulatory Enforcement Fairness Act of 1996 \(SBREFA\)](#) (5 U.S.C. 801 *et seq*) amended the RFA and requires EPA and the Occupational Safety and Health Administration (OSHA) to conduct panels during certain rulemaking efforts in order to receive input from small entities. Sullivan acknowledged that the SBREFA panels are often burdensome to the agencies, but emphasized the importance of reaching out to the community for help in writing rules.

The Office of Advocacy helps make the connection between small businesses and rule writers. Sullivan described an example of this type of collaboration regarding what he calls the “Bucket Truck Rule” – a complicated set of OSHA requirements for repair trucks. One regulated community member spent a day at his job and then 4 hours on the phone with SBA and OSHA staff discussing the technical details of the rule from his small business perspective. This resulted in OSHA considering the new technical information and making important changes to the regulation.

To rule-writing agencies, Sullivan suggests reaching out to small businesses in any way possible. He suggests embracing the methods of the younger generation (e.g., blogs and Web sites). He recommends involving the research community and contacting small businesses through newsletters, e-mail, roundtable meetings, staff liaisons, business journals, and other press. He strongly emphasized using SBA for small business contacts and a wealth of related data, noting that SBA cannot divulge any interagency confidential information to the public. SBA performs a great deal of outreach to small businesses through industry groups and trade associations; they can facilitate an informal mechanism to receive feedback on a potential rule. Furthermore, when gathering data from small businesses, SBA is committed to making sure that the data comply with rigorous data quality guidelines.

### Engaging Local Governments

*Bruce Tobey, Councilman, Gloucester, Massachusetts*

Bruce Tobey has spent 25 years in local government. He emphasized that the local level is where daily needs are met, where “the rubber hits the road,” and where theories are tested. He defines local government as any government entity except the federal government. In the next 25 years, he sees the need for an even more collaborative approach to regulatory development because much of the “low-hanging fruit” has been addressed, and the benefit-cost ratio is shrinking.

In order to gain efficiency and slow the decline of the benefit-cost ratio, Tobey feels it is important not only to engage the public but to partner with it. There is no single player involved in the many problems faced by government. Tobey is a supporter of the [Federal Advisory Committee Act \(FACA\)](#) because it is a robust tool that enables the involvement of local government participants. The consensus process driven by FACA is important because there is no winner or loser, rather negotiation toward achievable goals.

Tobey's stated that the two most important goals to achieve when engaging local governments are to communicate in plain language and build trust. He also emphasized his belief that development of local government advisory committees – such as [EPA's Local Government Advisory Committee](#) – is incredibly useful for communication of broad-based and productive feedback.

## **Getting Stakeholders to Work for You**

*William Russo, Department of Veterans Affairs*

William Russo of the [Department of Veterans Affairs \(VA\)](#) described how the VA worked with non-governmental entities to rewrite veteran compensation regulations. This project involved reviewing the current, outdated regulations and incorporating recent court decisions, agency manuals, and panel recommendations to produce a new, more clearly written regulation.

One of the goals of the project was to regularly meet with and consult with [Veterans Service Organizations \(VSOs\)](#). A VSO is often chartered by Congress and established to represent claimants seeking VA benefits. These organizations consist of non-attorney practitioners that represent veterans in claims cases at the local VA offices. VSO staff reference the compensation regulations every day, and often have a more thorough knowledge about the details of the rules than VA employees themselves. The purpose of including VSOs in the rulemaking process (e.g., holding meetings with them, communicating via e-mail and phone) was to keep them informed of the project's progress and to solicit suggestions.

After the regulation was proposed in the Federal Register (FR), VA staff met with every organization that submitted formal comments to discuss the comments and clarify any questions that the VA had. The VA staff were clear with the VSOs that they were not making any commitments regarding the issues discussed, just soliciting feedback. It was important to meet with *all* organizations that commented, so as to avoid any appearance of favoritism.

The benefits of this type of stakeholder input were significant. VA staff considered the VSOs a source of "free labor" to analyze the outcomes of the rulemaking and provide suggestions. Forty-one percent of the comments received resulted in changes to the draft regulation. Also, the project encouraged consensus early on, rather than dissent late in the process.

[See William Russo's PowerPoint slides.](#)

## **Summary of Roundtable Discussion**

The following issues and best practices were discussed during the roundtable discussion:

- Roundtable participants questioned whether the comments and information provided by stakeholders would be subject to the Freedom of Information Act (FOIA) when stakeholders are allowed to comment on an early draft of a regulation (or otherwise give comment before the formal notice and comment period). Participants agreed that a good practice would be to make it very clear at the beginning of the process that all information stakeholders provide could be made publicly available.
- Despite the disclaimer on [Regulations.gov](#) that comments will be made public, some people commenting on the VA regulations provided information that should be considered private (e.g., veterans' medical histories or personal contact information). Some agencies redact such information from comments before posting them publicly. Federal agencies need to achieve



consensus as to the legality of redacting any information provided in comments and develop a consistent procedure for doing so.

- As the Federal Docket Management System (FDMS) and Regulations.gov are improved, it is important to determine how to make it more useful in sharing information across agencies. It would be useful for agencies working on similar issues to be able to efficiently find technical information used in other rulemakings, rationales for making a decision, or responses to certain types of comments.

## Improving Agency Processes

This session featured three presentations and focused on tools to better manage regulatory development, including communication among staff, tracking, and management. Short summaries for each presentation are provided, along with a summary of the roundtable discussion that followed.

### Making Sure Staff Can Communicate Easily

*Trisha Choe, Department of Commerce*

The [Department of Commerce \(DOC\)](#) undertakes many rulemaking efforts each year. To facilitate communication on rulemaking between these scattered offices, Trisha Choe explained that DOC uses the Paperwork and Regulation Information Management Environment (PRIME), which was developed from a system previously deployed by the [Department of Transportation \(DOT\)](#).

PRIME is a secure, Web-based tracking system through which DOC staff can share the status of regulatory efforts and specific regulatory documents. Documents can be stored, transferred, approved, and tracked within PRIME. The system promotes collaboration on documents in progress (including the ability to store and use multiple versions of a document) and timely approval of completed document drafts. Any authorized user can access the system to view the status of a project, see all relevant milestones, and even generate a report on the current state of the rulemaking effort.

Documents can be transferred electronically through PRIME, allowing faster turnaround rates for document approval; this feature eliminates the need for expensive, time-consuming paper files and couriers. Ultimately, PRIME may help DOC to go completely paperless. By creating greater efficiency and transparency in the rulemaking process, PRIME has already saved significant time and money for DOC, and promises to save more in the future. Though PRIME is currently used primarily for document transmission and approval, DOC hopes that the system will eventually span the entire rulemaking process, from beginning to end.

[See Trisha Choe's PowerPoint slides.](#)

### Tracking and Measuring Our Development Process

*Alexander Cristofaro, EPA*

Alexander Cristofaro stated that regulation is a main product of EPA; the Agency is second only to DOT in the volume of regulations published. The regulations vary in size and scope such that only 126 of the 508 final regulations published in 2005 were "substantive actions" (i.e., they required the EPA Administrator's signature). In addition to the volume of regulations, the regulations often are complex, are expensive to develop and implement, and create controversy. Communication regarding regulations is difficult because the regulations may involve ambiguity with respect to risk and cost.

In developing its regulations, EPA seeks to balance many qualities: legal defensibility, simplicity, timeliness, ability to be implemented and enforced, clarity, comprehensiveness, analytical quality, and flexibility. The EPA Action Development Process (ADP) was developed to ensure that EPA publishes quality actions. It involves a number of milestones, including selecting the appropriate regulatory tier (or priority level), convening a regulatory workgroup, drafting an analytic blueprint, holding an early guidance meeting, selecting options, and conducting final agency review.

Because of the complexity of EPA rules and because of numerous time constraints (court orders, statutory requirements, management priorities, etc.), it is easy to fall into the practice of circumventing parts of the ADP. To help ensure that all offices follow the process, EPA's Office of Regulatory Policy and Management uses incentives, such as tracking, management reports, and regular meetings.

[See Alexander Cristofaro's PowerPoint slides.](#)

## Keeping Senior Management Focused

*Shirley Stroman, Federal Aviation Administration*

The [Federal Aviation Administration \(FAA\)](#) employs a [Flight Plan Performance Report](#) to help fulfill its mission of providing the safest, most efficient aerospace system in the world. The Flight Plan includes FAA's corporate strategy; report card; plan for moving forward; and specific, measurable performance targets to monitor progress and achievements. Shirley Stroman emphasized the Flight Plan as the key to keeping management focused. Stroman emphasized that FAA's key to keeping management focused is tying executive bonuses to how well the executives' respective offices meet Flight Plan goals. She also stressed that to achieve success in rulemaking it is important to communicate between staff and management.

FAA's regulatory management activities, carried out in the Office of Rulemaking, are an important part of its mission. The Office of Rulemaking partners with the office of primary responsibility (content expert), Office of Chief Counsel (legal support), and Office of Aviation Policy and Plans (economic support) to develop the rule. The rulemaking team includes a technical expert, attorney, rulemaking analyst, and economist.

Rulemaking begins as a Rulemaking Project Record (RPR), during which the RPR must be approved by the Rulemaking Management Council regarding the issues addressed, effects of the potential rule, and whether there are alternatives to rulemaking. At the end of the RPR process, the council approves the rulemaking and establishes a schedule, after which it follows the notice of proposed rulemaking (NPRM) and final rule processes relatively common to other agencies. At the end of the regulatory development process, all rules are routed through the Administrator's Office. Significant rules are sent to the parent agency (DOT). Stroman noted that constant and consistent communication from staff to management is inherent in the process.

There are two bodies of management oversight: the Rulemaking Steering Committee and the Rulemaking Management Council. The Rulemaking Steering Committee provides high-level oversight of the regulatory program set every fiscal year, which helps focus rulemaking efforts. This committee is at the Administrator level, and is charged with ensuring that rulemaking is consistent with the Flight Plan. The Rulemaking Management Council includes senior management. It approves the RPR, sets priorities, identifies critical issues, assigns resources, and provides accountability.

The FAA management plan is ISO-9001 certified for its quality management system, includes continuous improvement, and is audited periodically. Formal management review consists of monthly, executive-level dashboard reviews; weekly rules meetings attended by senior managers; principals' briefings that allow executives to comment on major policy decisions early in the process; and Continuous Improvement Team meetings. The Continuous Improvement Team meetings are used to identify best practices, innovative ideas, and opportunities for improvement.

[See Shirley Stroman's PowerPoint slides.](#)

## Summary of Roundtable Discussion

The following issues and best practices were discussed during the roundtable discussion:

- Participants stated a need for improvement in many of the E-Rulemaking tools they have used. Search functions are often difficult to use effectively; one participant noted that Regulations.gov is particularly difficult to use for locating a specific document. This problem underscores the need for more effective tools to share rulemaking resources between agencies.
- In various agencies today, documents are transferred by methods as diverse as disks, courier, and electronic transfer formats. Electronic transfers are the most time- and cost-effective methods; however, staff must be well trained in whatever method is used. For example, rule

publication can be significantly delayed when staff do not correctly format documents for inclusion in the FR.

- It is very difficult to obtain stakeholder participation for certain types of rules, whereas others receive thousands of comments. Some participants noted that they have had some success in soliciting participation in hearings, but that they must be well publicized via FR notices and other efforts.
- As Web-based organizational systems become more widely used, agencies will need to make efforts to fit such systems cleanly into their business management scheme. Existing systems are helpful, but more comprehensive tools, with improved search capability, version control, and other features, are needed in order to take full advantage of their potential. Common software that can be shared across agencies would also help reduce costs.
- Stakeholder involvement should be a critical part of an agency's process. At FAA, stakeholder input occurs in the rulemaking advisory committees, which include industry experts, as well as the NPRM process. Most particularly, the Aviation Policy Plans, which are responsible for economic analyses, obtain cost information from industry stakeholders.
- Providing measures with clear incentives for managers helps keep them focused on rulemaking. At FAA, executive management bonuses are tied to the extent to which managers meet schedule milestones, meaning that senior managers stay focused on tracking rulemaking efforts and follow up directly with the rulemaking team if it falls behind schedule.
- It is important to get management approval early and often. Participants also discussed the importance of clearly articulating whether a rule or regulation is needed as part of the management approval process. Participants noted that making managers responsible for the regulations in the planning stage maintains focus on the rulemaking process. Incorporating manager input in the planning stages also makes approval more predictable, and can prevent the use of limited resources on developing a regulation that will not be approved.
- Several participants commented on the challenge of monitoring the schedule and resources. Others expressed concern that primarily focusing on the schedule could lead to a regulation that, although developed more quickly, might not be as good as one developed with less focus on the schedule.

## Involving Stakeholders through Negotiated Rulemaking

This session featured three presentations on negotiated rulemaking. Short summaries for each presentation are provided, along with a summary of the roundtable discussion that followed.

### Strategies and Tools for Reaching Consensus

*Susan Podziba, Susan Podziba and Associates – Public Policy Mediation*

Susan Podziba stated that negotiated rulemaking often involves decision-makers convening stakeholders, engaging in roundtables, and subsequently drafting a proposed rule. This iterative process continues until a committee reaches consensus on a draft. There may be asides, caucuses, and other communication reflecting constant negotiation. Negotiated rulemaking requires flexibility and innovation.

The general goal is to get a draft of a rule written as soon as possible. In order to do this, the facilitator and group should set expectations and the direction, including boundaries and ground rules. If the group can reach consensus on draft regulatory text, the government agency will use it as the basis for the NPRM.

To facilitate negotiation, everyone at the table should have a stake in multiple issues. People who have an interest in only one or two issues should be invited to provide public comment but should not take part in the negotiations. Facilitators should understand the key interests of all stakeholder groups and any cross-cutting issues. Ideally, an assessment report document will be developed outlining and contextualizing issues and inferring manageability based on a survey of the universe of issues and stakeholders.

Podziba provided the following observations with respect to negotiated rulemaking:

- Imposing a deadline helps to bring about closure on difficult issues.
- Respect toward and among participants is critical.
- It is important for decision-makers to display leadership and communicate what is possible and/or expected.

If successful, negotiated rulemaking strengthens bonds between the governed and governing and functions as a mechanism of democracy.

[See Susan Podziba's PowerPoint slides.](#)

### Keys to Involving All Parties

*Edith Blackwell, Department of the Interior*

Edith Blackwell provided an overview of four separate rulemaking experiences at the [Department of Interior's Bureau of Indian Affairs \(BIA\)](#), all of which implemented negotiated rulemaking under a mandate by Congress. Congress also dictated membership of the various committees included in the negotiations. Among the major lessons learned are: (1) the convening process is important, (2) committee size and composition matters, and (3) deadlines can be useful.

The convening process helps ensure good-faith negotiations. When the membership on the rulemaking committees is dictated by Congress, it can take longer to foster good will among the members because the convening process is cut short. In several cases, a formal convening process could have helped ease negotiations. While dictating committee membership is within the jurisdiction of Congress, it reduces the value of the negotiation process. Furthermore, a predetermined membership meant that important stakeholders were sometimes left out. And, several of the negotiated rulemakings included committees of more than 40 people, leading to inefficiencies in negotiation. Both likely hurt the process because not all perspectives were represented and the large groups sometimes limited free-flowing people.

One final lesson: setting and adhering to deadlines is critical. In one case, lack of a deadline extended the process and may have made consensus difficult. It also increased the cost, in both money and time. In another case, the existence of a departmentally imposed deadline appeared to drive consensus.

## **Lessons Learned**

*Noah Connell, Occupational Safety and Health Administration*

Some standards are criticized for having the following flaws: (1) there are technical mistakes (e.g., something is substantively wrong; there are unintended inconsistencies with industry terms, or an issue was incorrectly resolved in the standard); or (2) there are important issues that were missed and therefore left unresolved. Noah Connell has found that negotiated rulemaking can help avoid both problems. In the context of negotiated rulemaking, OSHA brings together leading industry experts to broaden the scope of expertise, obtain a variety of views, and have a meaningful exchange of ideas on operations and technical issues as a precursor to rule drafting. Connell added that it can be particularly important to allow a dialogue within the industry to settle on terminology and resolve issues. This dialogue is important to have before the NPRM comes out because it cuts down on later work and develops a proposal that already accounts for various perspectives.

Some guidelines Connell proposed are:

- Set ground rules (e.g., procedures to follow, the definition of “consensus,” and how to fill a vacancy if a member leaves the committee).
- Consider defining consensus as something less than unanimity because otherwise you may not make real progress if the participants cannot work around an issue, or if you have a particularly polarizing issue.
- Make use of each stakeholder’s expertise.
- Set expectations early for what the standard must accomplish and for the committee’s role as the developer of concepts as opposed to “wordsmithing.”
- Have a high-ranking agency official come in and set the tone and goals.

For Connell, the motivation for negotiated rulemaking is more to avoid technical flaws and missed issues than to avoid litigation.

## **Summary of Roundtable Discussion**

The following issues and best practices were discussed during the roundtable discussion:

- While a transcript is useful for making an accurate record, it can hinder open discussion. A better practice is to develop summaries of the meetings that do not connect particular points to individual committee members.
- Solving an issue through ambiguity may be attractive to rule makers but presents major problems for enforcement. So, push the committee to be as clear and specific as possible.
- It is valuable to establish ground rules with respect to attendance, as well as for special contingencies such as the replacement of a committee member.
- Separate the development of concepts from the drafting of regulatory language. The committee’s expertise is not in drafting clear, enforceable regulatory language, and allowing members to focus on “wordsmithing,” particularly early in the negotiations, may prove problematic.
- It can be crucial at the beginning of the committee meetings to have a senior agency official summarize the purpose and goals of the committee and express appreciation for the participation of the members.

## Tapping Technology to Better Address Public Comments

This session featured three presentations that addressed how technology can help agencies receive, analyze, and respond to public comments. Short summaries for each presentation are provided, along with a summary of the roundtable discussion that followed.

### Receiving Comments on Proposed Rules

*John Moses, E-Rulemaking Program, Environmental Protection Agency*

The E-Rulemaking Program is intended to improve citizen access to participation in the rulemaking process. It is one of [26 e-government initiatives](#) resulting from the [E-Government Act of 2002](#) (P.L. 107-347). Currently, [Regulations.gov](#) is available for the public to comment on rulemakings from all agencies. From this Web site, the public can view the entire rulemaking docket, including FR notices, background information such as legal analyses, and public submissions. The public can also bookmark documents and request e-mail notifications when an item is added.

The Federal Docket Management System (FDMS) is a full-fledged content management system that manages the content for Regulations.gov. It provides many capabilities for agency users, such as workflow management and full-text searches. In the future, the intent is to provide more tools, best practices, and templates for rule writers on FDMS to help improve the regulatory process. Developers are also working on future capabilities for public users such as full-text searches and comment categorization. Moses noted that the approach for developing FDMS is highly collaborative. So far, 25 agencies have implemented the system and participate in its development.

FDMS currently works as follows. The rulemaking agency sends the regulatory document (e.g., proposed or final rule notice) to the Office of the Federal Register (OFR). OFR edits and publishes the document in the FR. FDMS automatically captures the documents electronically published by OFR, and each agency's staff makes them available for the public to submit comments. When comments are submitted, an agency staff member must review the comments before they are publicly posted. Paper documents mailed to the docket are scanned and uploaded. Moses noted that the electronic record archiving system used by FDMS has been approved by the National Archives and Records Administration – meaning that agencies no longer have to maintain paper copies of docket documents (a significant cost savings).

The use of Regulations.gov is showing an upward trend. Regulations.gov benefits the public because it makes the rulemaking process more accessible. It provides “one-stop” access to information on federal activities and increases the transparency of the rulemaking process. The E-Rulemaking Program strives to continue making the system more useful by expanding workflow capabilities and providing version control. There is also the possibility of making the public comment process more like a “wiki” (i.e., allowing interactive comments that build upon one another).

[See John Moses' PowerPoint slides.](#)

### Analyzing Comments

*Stuart Shulman, University of Pittsburgh*

[Stuart Shulman](#) (University of Pittsburgh) presented tools developed by the [eRulemaking Research Group](#) that help agencies analyze public comments more efficiently. Due to the visibility of some federal rulemakings, many non-profit organizations sponsor e-mail campaigns that result in thousands or even hundreds of thousands of identical or near-identical submissions. Shulman suggested that mass e-mail campaigns may do more harm than good to the public participation process. Often, they dramatically increase the number of submissions over a relatively short period. The sheer number of duplicate (or near duplicate) submissions increases the likelihood that unique, substantive comments could be overlooked.

Analyzing comments electronically saves significant amounts of time and effort. Government officials often estimate that reviewing several thousand comments takes several months of staff time. An electronic approach helps find and process duplicates more accurately. The software is able to detect duplicates, as well as identify similar submissions that include a limited amount of unique text. Highlighting is done by algorithm to indicate added and deleted text from form letters. Thus, agency staff can spend less time determining what the unique comments are and more time addressing them.

Software can maintain a log of what an agency has read, which can be important for litigation purposes. Also, by structuring the navigation to drill down, agencies are able to group comments by opinion and author type, which is important for stakeholder analysis. Other capabilities include full-text search and workflow management.

Tools are neutral, and are only a mechanism for agencies to better analyze comments. The decision-making process is unchanged. Shulman advocates creating tools that allow those who take the process seriously to be heard, and also encourages use of technology to collaborate and formulate better comments. Agencies need to determine what they need to know with respect to public comments, and then software developers can determine how technology can help provide the answers.

[See Stuart Shulman's PowerPoint slides.](#)

## **Responding to Comments**

*Sonia Brubaker and Greg Mallon, Tetra Tech, Inc.*

To support EPA's Office of Water (OW) through the public comment period, Tetra Tech developed a system to categorize and respond to public comments. Generally, EPA hires a contractor to develop a simple database, on a rule-specific basis, to manage public comments. Realizing that they could achieve economies of scale by creating a more robust database for all rules, OW asked Tetra Tech to develop a more sophisticated system. It is a Web-based application supported by ColdFusion.

To support the database, Tetra Tech staff code comments by EPA-determined categories. Then, EPA staff draft, edit, and track responses. EPA and Tetra Tech collaborate to ensure comments are coded correctly and to enhance the database. The system provides the ability to search comments by keyword, code, audience, and coder. When all comments have been reviewed and all responses created, the system generates a pre-formatted comment/response report in either PDF or Microsoft Word.

[See Sonia Brubaker and Greg Mallon's PowerPoint slides.](#)

## **Summary of Roundtable Discussion**

The following issues and best practices were discussed during the roundtable discussion:

- There needs to be an educational component to the Regulations.gov Web site to help better engage members of the public and make them better informed participants in the regulatory process. One suggestion is to develop educational materials that clearly distinguish the rulemaking process (federal agencies) from the lawmaking process (Congress). The public should be made aware of the roles of each body of government.
- Given the increasing use of mass commenting campaigns, agencies need a consistent approach for weighting/valuing the volume of repetitive comments received on a particular issue.
- One agency representative noted that commenters have begun answering each other in the electronic dockets. This is an area of public participation that should be explored further. Agencies need to determine if, under the Administrative Procedures Act, "comments on comments" are considered comments themselves, which would then require a response from the agency. Furthermore, it would help to analyze whether an iterative comment process would



provide benefits to regulatory development. If so, we should invest resources to enable these online discussions.

- Interactive, real-time monitoring of comments by agency staff has the potential to help clarify commenters' misunderstandings and generate useful feedback. However, processes need to ensure that agency responses are appropriately reviewed. This is important because the language used in the FR notice for a rulemaking is always subject to layers of review initially, and any additional commentary by agency staff may be considered official agency policy.
- For technology-based solutions, it is critical to bridge the divide between program and IT staff.

## Combining Regulation with Collaborative Programs

This session featured two presentations on collaborative programs as an alternative or complement to regulation. Short summaries for each presentation are provided, along with a summary of the roundtable discussion that followed.

### Applying Lessons from Collaborative Program Negotiations

*Tom Tyler, EPA*

Tom Tyler described the [National Vehicle Mercury Switch Recovery Program](#) as an example of a partnership program. It works to remove mercury-containing switches used in convenience lighting and some anti-lock braking systems in millions of vehicles manufactured prior to 2003. These mercury switches were not regulated prior to the program and are not now because of the partnership that has been forged. Cumulatively, the switches would have accounted for 75 tons of mercury emissions over the next 15 years. The program employs market incentives to remove them when a car is scrapped. Mercury switches were voluntarily phased out of new vehicles in 2003, so this effort focuses on earlier vehicle models.

At the end of a vehicle's useful life (approximately 10-15 years), it is dismantled and the steel hulk is recycled. In the United States, there are roughly 6,000-12,000 auto dismantlers, many of which are small businesses and are organized into multiple smaller trade associations. The auto dismantlers send the steel hulk to scrap recyclers, which shred the steel down and resell it to steelmakers.

Prior to this program, the mercury switches in vehicles were not removed before shredding, and therefore the mercury was a part of the steel recycling stream sold to the steel mills. During the steelmaking process, particularly in the electric arc furnace, the mercury was emitted into the air and contributed to a significant source of mercury air emissions. Mercury emissions are not captured as part of air pollution regulations, and even if there were a mercury-specific regulation for air emissions, there is currently no successful pollution control technology.

States had begun to address the mercury switch problem, but regulations varied from state to state. The pressure to address this issue nationwide prompted EPA's partnership program. The effort required organization and coordination between offices in EPA, and with key stakeholders (e.g., states, environmental groups, industry associations). An inter-office working group on mercury applications was formed, which included all media offices, the Office of General Counsel (OGC), the Office of Research and Development (ORD), and the EPA Regions. Tyler noted that participation by the stakeholders, and especially states with their own mercury switch programs, provided much of the data required by the working group. EPA hired professional facilitators to lead discussions among the partners and keep up pressure to meet their deadlines.

The result was a Memorandum of Understanding (MOU) that outlines the responsibilities of parties and the checks and balances associated with the program activities. Under the MOU, automakers created the [End of Life Vehicle Solutions Corporation \(ELVS\)](#), which provides dismantlers with information and supplies needed for switch removal, collection, and transportation. Participating dismantlers remove mercury-containing switches and ship them to ELVS in exchange for the ability to market reduced-mercury scrap and other financial incentives. Steelmakers educate and encourage their supply chain to participate, and take steps to purchase reduced-mercury scrap.

In 2006, EPA proposed a rule that would impose requirements on future use of mercury-containing switches in vehicles, and in 2007, EPA will propose a national emission standard for hazardous air pollutants from electric arc furnaces in steel mills. Under the proposed standard, steelmakers would have an option to choose reduced-mercury scrap – scrap resulting from the program – as a means of meeting national mercury air standards.

As part of the checks and balances, ELVS maintains a Web site with information that includes a state-by-state list of dismantlers and scrap recyclers participating in the National Vehicle Mercury Switch Recovery Program.

## **Supporting Regulations with Collaborative Programs**

*Stephan Sylvan, EPA*

EPA currently operates more than 50 collaborative programs with a wide range of activities. EPA defines a collaborative program as: (1) motivating specific action steps; (2) not compelled by law; and (3) Agency-led. Stephan Sylvan explained that the programs are part of a “policy toolbox,” which may include tools such as regulation, compliance assistance, economic incentives, grant programs, and education.

In everyday life, we are already interacting with successful partnership program results, such as the hibernate setting on computers, the recycled content of newspaper, and the low-flow and energy-efficient fixtures in our home and office. Sylvan outlined factors that can lead an agency to consider a more collaborative, partnership-type program to complement the more traditional regulatory approach:

- A regulation may be more costly, or political desire/will for a regulation may be lacking.
- Extensive regulation is already in place but does not cover key entities.
- Regulatory process is too slow or inflexible for the problem (e.g., technology is changing).
- There is a disconnect between responsibility and influence.
- Education does not deliver results soon enough, or it may work but does not resolve the issue.

Collaborative programs often help to fill regulatory “gaps.” They can help prepare for a regulation (e.g., if technology in an upcoming regulation is too expensive, a partnership approach may increase technology diffusion into the marketplace), promote early action before a regulation (e.g., a diesel rule for trucks that creates a phasing-out period prior to regulatory action), augment the regulation (e.g., extending the regulation to enterprises outside of its scope), or substitute for a regulation when there are too many entities to regulate or when sufficient progress is possible without a regulation..

To include a program-level view of collaborative programs, Sylvan outlined key characteristics for three programs led by EPA, noting the goals, targets, value proposition (what EPA offers and what the partner offers), key design elements, and results. From the program perspective, using a partnership approach makes the most sense when: (1) the problem, the goal, and the target decision-makers are clearly defined; (2) immediate and universal change in behavior is not necessary; (3) there exists a strong program design logic with significant results potential; (4) resources are allocated; (5) the Agency is the appropriate leader of the program; and (6) there is proper coordination. These programs may rely on a different skill-set from traditional rulemaking, emphasizing marketing, public relations, and outward coalition builders for success.

Overall, the partnership approach is most effective when it combines people with traditional rulemaking skills and roles (e.g., engineering, scientific, economic, financial, and legal analysis) and non-traditional skills and roles (e.g., entrepreneurial leadership, marketing/branding strategy, recruiting/sales/coalition building, communications materials development, event planning, and customer service). The partnership approach can be most effective with a broad, deep, and strategic understanding of the industry and “intervention points” for possible government and partner input.

[See Stephan Sylvan's PowerPoint slides.](#)

## **Summary of Roundtable Discussion**

The following issues and best practices were discussed during the roundtable discussion:

- Participants expressed interest in understanding the typical timeframe for these program activities. For the National Vehicle Mercury Switch Recovery Program, Tom Tyler noted that the

working group was unable to meet most of its deadlines. Stephan Sylvan added that every program takes differing amounts of time at start-up.

- In the situation of a partnership program that has reached a plateau or has maximized the benefits for the costs, participants were interested in knowing how the programs foster higher levels for participation. Stephan Sylvan noted that for the [Energy Star](#) program, the levels of energy efficiency are established to qualify 15-20 percent of the marketplace, and when that marketplace increases to 45-50 percent participation, the levels are ratcheted up.
- Participants discussed the data on consumer “buy-in” behavior, noting that evidence shows consumers are typically not willing to pay a higher price for environmental attributes. In these situations, participants agreed that it is important to incorporate the environmental attribute at the manufacturing level, and not rely on consumer behavior, which can be extremely costly to change.
- Participants discussed a potential partnership approach to restrict trucks from driving over certain problematic railroad crossings. A participant from DOT noted that in the 1990s DOT considered a proposal that would have required all state governments to change the configuration of dangerous bridges or change the signage near these particular crossings. Instead, DOT is considering a partnership approach whereby they would incorporate the coordinates of the bridge crossings into navigation software so that trucks are no longer routed over them. Participants discussed whether this would add time to trucking routes, but noted that limitations for trucks are already established due to other reasons (e.g., hazardous material routes, appropriate bridge ratings), and so this would incrementally save time through avoidance of the issue. Participants agreed this was an interesting idea to pursue.
- A participant from OSHA outlined a partnership established to prevent accidents and fatalities from less common causes, as current regulations cover only the common causes. As part of the partnership, six electrical line construction contractors signed an agreement to reduce the incident and fatality rate. The partnership reviewed the accident data and statistics to identify what types of accidents occur most frequently. The partners and OSHA then produced an OSHA safety program, which included a “train-the-trainer” course on application of the regulations. The results of this partnership have decreased the fatality rate for electrical line workers.
- The OSHA participant noted that it was difficult to get consensus from all partners on the notion of increasing the safety program. Stephan Sylvan responded that while a partnership program should consult with all stakeholders, it may not be possible to consult with all potential stakeholders at the same time. In the initial stages, it is common for such program to work more closely with “early adopters” in a particular market, industry, etc. Trade associations may be great partners once a critical number of their members are ready to support the initiative.

## Achieving Effectiveness and Efficiency in Regulatory Development

This session featured three presentations that addressed obstacles to developing efficient regulations, as well as model solutions. Short summaries for each presentation are provided, along with a summary of the roundtable discussion that followed.

### The Real Obstacles to Efficiency

*Fred Emery and Andrew Emery, The Regulatory Group*

Fred Emery and Andrew Emery, consultants specializing in regulation writing and policy development, described the key obstacles that make the rulemaking process difficult:

- Respect: A number of organizations and institutions provide advice on rulemaking, but there is little appreciation for how difficult a task it is.
- Complexity: Every rulemaking is different, with its own unique challenges.
- Communication: Early, clear communication is needed, both within the agency and to outside stakeholders.
- Decision-making: It is often time consuming to get agency heads to make a decision.
- Driving force: Every rulemaking must have a motivation; there can also be roadblocks that stall the process for long periods of time.

The presenters compared the rulemaking procedures of 1965 to those of today, noting that many statutes, executive orders, and guidance practices have been established over the past 40 years. It is often a major reason why rulemaking is slow.

The presenters provided an overview of the rulemaking process, as required under the [Administrative Procedures Act](#) (5 U.S.C. 551 *et seq.*), strongly emphasizing coordination between steps as an important solution to overcoming the obstacles in rulemaking. Getting upper management to make a decision is often a big obstacle; clear communication and coordination from the beginning is essential.

[See Fred Emery and Andrew Emery's PowerPoint slides.](#)

### Regulatory Reform in Nova Scotia: Measuring Regulatory Burden and Marking Progress

*Mary Belliveau, Nova Scotia Better Regulation Initiative*

Nova Scotia is undertaking the [Better Regulation Initiative](#) to accomplish several goals: identify and reduce burden, promote compliance, improve regulations, and report progress. Using a Better Regulation Index based on hours of administrative burden, the initiative works to determine where best they can decrease the burden on business. Nova Scotia has also established targets for turnaround on government services, development of compliance promotion plans, and establishment of online permitting tools. Finally, government staff have conducted surveys to measure the cost and perception of burden and service levels.

There are several key lessons learned: developing good relationship with businesses, building capacity with public servants, and garnering support from officials and managers are critical. To ensure long-term success, Nova Scotia is working on connecting their reduction of regulatory burden with performance management measures.

[See Mary Belliveau's PowerPoint slides.](#)

## **Achieving Effectiveness and Efficiency in Regulatory Development – The E-Agenda**

*Wendy Liberante, Office of Management and Budget*

The E-Agenda initiative is an effort to disseminate the contents of the “Unified Agenda of Federal Regulatory and Deregulatory Actions” via the Internet. The Unified Agenda is published twice per year (fall and spring) and lists the regulatory actions that agencies are developing or have recently completed.

The E-Agenda will increase effectiveness and efficiency by increasing transparency to the public; provide search capabilities; make regulatory documents easier to access and understand; and link the Unified Agenda with regulatory Web sites and dockets. It will ultimately lead to greater opportunities for public participation in the regulatory process by allowing citizens (e.g., small business owners) to more easily discover what proposed regulatory activities may affect them.

The E-Agenda will not replace publication to the Federal Register, though it is tied to Regulations.gov and other e-resources. Instead, it will provide a comprehensive collection of supporting materials at marginal added cost.

[See Wendy Liberante's PowerPoint slides.](#)

### **Summary of Roundtable Discussion**

- Agency staff members could contribute to the E-Agenda effort by providing information in an understandable, meaningful format. It is important to plan and coordinate the regulatory process in order to make it more accessible and open to the public.
- Several characteristics were key to the changes in Nova Scotia: the small size and population of the province, the use of strategies that tied together the environment and economics, and the participation and commitment of a government official.

## Concluding Session

The conference ended with an informal session led by Rick Otis, the EPA Deputy Associate Administrator for Policy, Economics, and Innovation. Otis touched upon possible next steps based on the conference sessions. Finally, participants were invited to suggest additional best practices and focus areas, and then were asked to cast up to ten ballots for the concepts that deserve attention and follow-up.

### Parting Thoughts: Where Do We Go from Here?

*Rick Otis, Environmental Protection Agency*

To build upon Neil Kerwin's opening remarks, Rick Otis reiterated that regulatory development is an underserved profession. For all the attention placed on policy analysis by various graduate schools, few focus on the process of regulatory development. To fill that gap, Kerwin created the [Center for the Study of Rulemaking at American University](#), which was an important step in raising the profile of regulatory development within the public policy field. Otis encouraged participants to read Kerwin's work, "[The Management of Regulation Development: Out of the Shadows](#)," which is part of the IBM Center for the Business of Government series.

Information technology is woefully underused in regulatory development. Agencies are just beginning to realize its potential. The need for better technology solutions was a common theme throughout the conference, and Otis encouraged better dialogue between program staff and IT staff, who often talk past each other.

The conference was an important first step in establishing and promoting a dialogue among the federal regulatory community. Participants indicated a need for ongoing collaboration, beyond just an annual meeting, which would formalize and sustain the interaction. Potential avenues include a Web site, e-mail list, or even a more formal organization. In addition to other formats, Otis encouraged participants to make suggestions for different staff levels to learn about regulatory development and build related skills, from the career manager to the recent master's degree graduate.

### Group Voting

The following table summarizes the results of the group voting exercise, where each participant could cast up to ten ballots for concepts from the conference that he/she would like to see addressed further.

Rank	Concept	Votes	
		Number	Percentage
1	Create a "regulatory development" profession	93	21
2	Need to create forums for ongoing dialogue	86	20
3	Analyses must inform decision-making and not justify it	53	12
4	Engage the public pre-proposal	44	10
5	Need to define how to use technology to make rule writing more efficient	36	8
6	Need to define how to use technology to improve public participation	36	8
7	Need to determine how best to obtain and sustain management commitment	29	7

8	Need to consider alternative approaches to rulemaking (e.g., economic incentives, market-based approaches)	22	5
9	Must keep in mind what the public wants/needs and recognize this may be different from internal agency needs	19	4
10	Need to define how to make our processes more transparent	15	3